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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,261	11/20/2001	Eamonn P. Hobbs	ANGIO P-26	9573
26418	7590	08/10/2007		
REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 08/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/989,261	<b>Applicant(s)</b> HOBBS ET AL	
	<b>Examiner</b> Laura C. Schell	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 30-34 and 66-80 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 66, 68, 70, 72, 76 and 78 is/are rejected.
- 7) ☒ Claim(s) 67, 69, 71, 73-75, 77 is/are objected to.
- 8) ☒ Claim(s) 79-84 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 66, 68, 70, 72 and 76 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. (US Patent No. 6,749,628). Callol discloses a catheter assembly (Fig. 59) comprising: one tube (532) having a sidewall and a longitudinal companion member (533), said tube and said companion member coupled to and contacting one another at surfaces thereof along a predetermined zone (Fig. 59 is merely a schematic of the catheter assembly showing the engagement member and how it is positioned within assembly. If one refers to actual drawings of the possible assemblies, i.e. Figs. 46 or 54 for example, it is clear that though the schematics do not show the members contacting one another, for the purpose of clear illustration, the

Art Unit: 3767

drawings, not schematics, are more detailed and show that the tube and companion members are in contact with one another), and a linear engagement member (536) extending longitudinally within said sidewall of said tube and through said companion member, said tube and said companion member held together solely at said zone (Fig. 59), the distal most end of the linear engagement member being embedded in said sidewall of said tube (Fig. 59), said tube, said companion member and said linear engagement member extending proximal of said zone by an amount sufficient to extend out of the body of a patient in whom the catheter is implanted (col. 41, lines 23-25 disclose that the joining wire/linear engagement member extends proximally out to the hub of the catheter which therefore means that it extends out the body of the patient, as the hub of a catheter is not placed within the patient as this is what is grasped and held in place during procedures), said linear engagement member being accessible upon cutting through said sidewall within which said linear engagement member is embedded, thereby permitting withdrawal of said linear engagement member to cause said tube and said companion member to disconnect and permit separate, independent withdrawal of said tube and said companion member from a patient (if the operator cuts into the catheter, the catheters are perfectly capable of being separated this way).

While Callol discloses that the proximal end of the linear engagement member is attached to the wall of the tube (as Fig. 59 discloses that the distal most end of the linear engagement member/joining wire 536 is embedded in the tube's sidewall (532) and col. 41, lines 23- 27 disclose that the joining wire extends through the proximal end of 533 to the hub where it is locked in place to the wall of the hub further described in

Art Unit: 3767

col. 28, lines 12- 28), it does not disclose that the proximal end of the linear engagement member is embedded in the wall of the tube. Callol, does, however, disclose that the distal end of the linear engagement member is embedded in the wall of the tube, as shown in Fig. 59. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the proximal end of the linear engagement member of Callol, by embedding it in the wall of the tube, just as the distal end is embedded, as taught by Callol, in order to provide another means of securement.

In reference to claim 68, Callol discloses that the surfaces at said zone are flat surfaces (fig. 59).

In reference to claim 76, Callol discloses that the zone is located on a portion of the catheter that is located within a patient when the catheter is implanted in a patient (Fig. 59).

In reference to claim 78, Callol discloses that the linear engagement member is a surgical suture (Fig. 59).

In reference to claims 70 and 72, Callol discloses the device substantially as claimed including a linear engagement member (Fig. 59, 536) extending proximally to a position outside the patient when the catheter is implanted in the patient (col. 41, lines 23-25 disclose the linear engagement member extends proximally to the hub which is located outside of the patient), said wire having a proximal end (col. 41, lines 23-25), said wire being withdrawn by accessing and pulling on said proximal end (col. 41, lines 37-40). Callol, however, does not disclose that the linear member is a set of two wires. It

Art Unit: 3767

would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Callol by adding another linear engagement member such that there would be two wires for further support of the engagement and since it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

### ***Allowable Subject Matter***

Claims 79- 84 are allowed. The allowable subject matter not found within the prior art is: a dialysis catheter with a linear engagement member with both its proximal and distal most ends embedded in at least one of the sidewalls of the tubes, and a catheter assembly with the above named patentably distinct features in addition to a flexible separating prong and a recess on the surface of the other tube for the abutment of the prong.

Claim 67, 69, 71, 73-75 and 77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments with respect to claims 66-84 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references were found which are pertinent to

Art Unit: 3767

Applicant's filed claims: Zawacki et al. (US 2004/0167463) and Graft et al. (US 2005/0054990). Both references disclose catheter assemblies in which two tubes are joined together by a linear engagement member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*